

NORTH DAKOTA DEPARTMENT OF HEALTH
Division of Air Quality

RADIOACTIVE MATERIAL
LICENSING GUIDE

Non-portable (Level) Gauges

(Revised February 2, 2006)

Table of Contents

	<u>Page</u>
I. Introduction	1
II. Filing an Application	1
III. Radioactive Material License Application Form SFN 8418 (RCP-10)(9-01)	2
Item 1: Applicant and Locations of Use	2
Item 4: Personnel	2
Item 5: Radiation Safety Officer	2
Item 6: Materials	3
Item 7: Uses	3
Items 8 & 9: Qualifications of Personnel	3
Item 10 & 11: Radiation Detection Instruments	3
Item 12: Personnel Monitoring	4
Item 13: Facilities and Equipment	5
Item 14: Radiation Protection Program	5
Item 15: Waste Disposal	7
IV. Amendment and Renewal of Licenses	7
Appendix A - Specific Authorizations	8
Appendix B - Radiation Training Guidelines	10

I. INTRODUCTION

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of radioactive material contained in non-portable gauging devices such as gauges mounted in "fixed" locations, for measurement and/or control of material density, flow, level, thickness, weight, etc. The Department's rules, listed below, apply to radioactive material licensees and should be used in conjunction with this guide. The applicant should carefully read the rules. This guide does not substitute for an understanding of the rules.

- A. Chapter 33-10-10, "Notices, Instructions, and Reports to Workers - Inspections"
- B. Chapter 33-10-04.1, "Standards for Protection Against Radiation"
- C. Chapter 33-10-03, "Licensing of Radioactive Material"
- D. Chapter 33-10-11, "Fees for Issuance of License and Registration Certificates and Inspections"

All information submitted as part of this application will be subject to North Dakota's Open Record Statute, Section 44-04-18, "Access to public Records - Penalty" of the North Dakota Century Code. The information will be available to the public unless confidentiality is granted by the Department. Requests for confidentiality must be submitted in accordance with Section 23-20.1-09.1, "Confidentiality of Records" of the North Dakota Century Code. Confidentiality requests will be considered in accordance with the above-mentioned statutes.

II. FILING AN APPLICATION

The information submitted must be sufficient to allow the Department to determine that the proposed equipment, facilities, procedures, and controls are adequate to protect health and minimize danger to life and property. The information submitted must be complete and should pertain to the specific activities for which authorization is sought. Submission of incomplete information will result in delays because of the correspondence necessary to obtain supplemental information. Applications should be mailed to:

North Dakota Department of Health
Div. of Air Quality
918 East Divide Avenue, 2nd Floor
Bismarck ND 58501-1947
Phone: 701-328-5188
Fax: 701-328-5185

Since licensees are required to comply with Department rules, license conditions, and the content of the submitted application, at least one copy of all information submitted to the Department should be kept by the applicant for reference.

III. RADIOACTIVE MATERIAL LICENSE APPLICATION FORM 8418

The application (Form 8418) should be completed following the instructions provided with the form. The signed original copy should be filed with the Department and one copy kept by the applicant. Since the space provided on the form is limited, additional sheets should be appended as necessary. Supplemental information should be labeled to identify the applicant and reference the items for which information is being given. The following comments deal with the indicated items of the Form 8418.

Item 1 - Applicant and Locations of Use - The applicant corporation or other legal entity should be specified by name and mailing address in Item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

The actual sites of use should be given in 1(b). Permanent facilities such as field office storage areas for the gauges or devices should be identified in 1(b) by street address, city, and state.

Attach additional sheets if more space is needed.

Item 4 - Personnel - Each person who will use radioactive material should be named.

Item 5 - Radiation Safety Officer - Normally, it is not necessary for users of non-portable gauging devices to designate a radiation Safety officer unless there are multiple users and gauges within the plant or facility. However, the applicant should list the name in Item 5 of an individual user, supervisor, foreman, or other designated individual who has been assigned responsibilities for determining that:

- A. All radioactive materials, sealed sources, and devices in use and/or in the possession of the applicant are limited to those listed in the license and are being used for the purpose specified in the license.
- B. Only those individuals authorized by the license use or supervise use of the devices.
- C. Periodic leak tests of the sealed sources are conducted as required by the license.
- D. The established "lock-out" procedures are followed during

maintenance or repairs on or around the pipes, tanks, vessels, conveyors, etc., to prevent individuals from entering the radiation beams. (As shown in Item 14 of this guide, "lock-out" procedures must be described in the application for certain types of devices.)

Item 6 - Materials - Each sealed source to be used in a given gauge or device should be specified by isotope, (for example, cesium-137, radium-226, etc.), manufacturer and model number of each source, and activity in either millicuries or microcuries. The total number of each of the listed model number sources should be specified.

Item 7 - Uses - The manufacturer's name and model number of each gauge or device utilizing the sources listed in Item 6 must be specified and keyed to the listed source. In addition, the purpose for which the gauges or devices will be used must be stated.

Item 8 & 9 - Qualifications of Personnel - The training and/or experience of each person named in Items 4 and 5 must be submitted. User qualifications should include, as a minimum, the completion of the device manufacturer's training course or program. See Appendix B for Radiation Training Guidelines.

If the applicant desires to provide in-house training for his own personnel, a description of the training must be provided. Included in the description of in-house training should be:

- A. The name(s), training, and experience of the individual(s) providing formal training.
- B. An outline of the formal training and on-the-job training to be provided, including the duration of the training.
- C. The means of determining when the trainee has satisfactorily completed the training and is capable of carrying out the radiation safety responsibilities required by the license.

Items 10 & 11 - Radiation Detection Instruments - Radiation detection instruments such as survey meters are not normally required if the applicant plans only to use the gauges and devices for their intended use and does not plan to perform maintenance on the gauges and/or devices involving access to the sources and/or source holders. However, if the applicant does intend to perform maintenance, the survey instrument(s) that will be available at each site where maintenance will be performed should be specified. At least one low range beta-gamma (0-20 or 0-50 mR/hr) survey meter should be available at each maintenance area for monitoring during and following the maintenance procedures.

If radiation survey meters are necessary for the proposed activity, survey meter calibration provisions should be

described. If the applicant intends to contract out the calibration of instruments, the name, address, and license number of the calibration firm should be specified together with the frequency of the calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Department. If information has not been filed, information concerning calibration procedures should be obtained and submitted.

If the applicant intends to perform the survey instrument calibrations, state the frequency and describe the methods and procedures for performing the calibrations.

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instrument function should be supplemented every six months with a calibration of each scale of each instrument. To properly calibrate an instrument its response must be checked at two points located approximately one-third and two-thirds of full scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for the points checked. Readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

The description of applicant's calibration procedures should include, as a minimum:

- A. The manufacturer and model number of each radiation source to be used,
- B. The nuclide and quantity of radioactive material contained in the source,
- C. The accuracy of the source(s). (The traceability of the source to a primary standard should be provided.),
- D. The step-by-step procedures for calibration, including associated radiation safety procedures, and

- E. The name(s) and pertinent experience of person(s) who will perform the calibrations.

Item 12 - Personnel Monitoring - For routine use of devices, the use of personnel monitoring devices (film badges or thermoluminescent dosimeters) are not normally required. Applicants who want to perform non-routine activities which will require the use of personnel monitoring devices should provide the name of the supplier of the monitoring devices and the frequency of exchange for processing by the supplier. For guidance concerning personnel monitoring requirements, the applicant should refer to Subsection 33-10-04.1-09.2 of the rules.

Item 13 - Facilities and Equipment - The applicant should provide a description of the equipment and facilities to utilize the devices containing the radioactive material. A simple annotated sketch or drawing showing where each device is installed and the location of adjacent ladders, aisles, or work areas employees will occupy should be provided.

Item 14 - Radiation Protection Program - For routine use of devices, the applicant should provide the following information:

- A. The name of the company or person who will conduct servicing operations involving installations, relocations, removals, initial radiation surveys, maintenance, repairs, and removal of the devices containing licensed material and installation, replacement, and disposal of sealed sources containing licensed material used in the devices. If any of these operations will be performed by someone other than the supplier of the device, the applicant should provide the name and number of the NRC or Agreement State license which authorizes performance of these operations. Applicants who request authorization to perform any of the above servicing operations should provide the information described in Appendix A of this guide.
- B. A description of how access to the devices containing radioactive material will be controlled. (Barriers, warning signs, remote or inaccessible locations, control by individual users, etc.)
- C. For use of a device where it is possible for a major portion of an individual's body to receive exposure to the radiation beam from the device, a description of "lock-out" procedures, (i.e., procedures for preventing employees from entering the radiation beam during maintenance, repairs, or other work on or around the bin, tank, hopper, pipe, etc., on which the device is mounted) should be submitted. If the device shutter or switch is locked, bolted, "tagged-off", etc., until the work is completed, the applicant should describe this and provide

the name of the individual(s) responsible for enforcing this procedure.

- D. The procedures for leak testing of the sealed sources. If the supplier of the devices containing the sealed sources will perform leak tests of the sealed sources in the applicant's facility, it is only necessary for the applicant to state this and to specify the frequency of the leak tests. If the applicant plans to use a leak test kit, the name of the supplier and the model number of the leak test kit should be specified. Applicants who will perform their own leak tests, i.e., collect the leak test wipes and analyze the wipes, should provide the information described in Appendix A. of this guide.

The required frequencies for leak testing of sealed sources in non-portable devices range from three months for alpha emitting radioactive material to six months for beta-gamma emitters. Some sealed source/device combinations containing beta-gamma emitters have leak test frequencies not to exceed three years. Information concerning sealed sources and devices which have three-year leak test frequencies may be obtained from suppliers and/or manufacturers. Unless a specific request for the three-year leak test frequency is included in the application, a six-month frequency will be specified in the license.

- E. ALARA:

Ensuring that Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)

Describe the management policy and organizational structure related to ensuring that occupational radiation exposures are ALARA. Describe the applicable responsibilities and the related activities to be conducted by the individuals having responsibility for radiation protection. Indicate whether, and if so how, the guidance given in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," will be followed; if it will not be followed, describe the specific alternative approaches to be used.

Please describe special measures that will be undertaken to limit exposure for female employees of child-bearing ages.

The application should contain a commitment by the applicant that all safety-related operations will be conducted in conformance with detailed written procedures. A detailed description of the procedures should be provided.

Item 15 - Waste Disposal - In the event the sealed sources will no longer be needed, the applicant should specify his means of disposal. Sealed sources containing radioactive material may be returned to the manufacturer, transferred to another licensee authorized to possess the specific quantity and form being transferred, or transferred to a licensed waste disposal firm.

IV. AMENDMENT AND RENEWAL OF LICENSES

Applications for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requested changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. If an application for license renewal is filed thirty days or more before license expiration, the existing license remains in effect until the new application has been finally acted upon by the Department.

Renewal applications should be filed using Form SFN 8418 and should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document by date and indicate pertinent information by page and paragraph.

Upon submitting an initial application, the appropriate fee should accompany the application as directed in Chapter 33-10-11 of the rules. There is no fee for license renewal.

The amendment fee is \$140.

The base annual fee for a fixed-gauge license is \$800 (an additional \$100 is added for each extra licensed location and an additional \$150 is added if more than 25 devices are possessed under the license). The annual fee must be paid by January 1 each year the license is active.

All fee payments shall be made by check, draft, or money order made payable to the North Dakota Department of Health. All fees are non-refundable and a late charge may be assessed.

APPENDIX A - SPECIFIC AUTHORIZATIONS

This appendix describes the information applicants must provide upon application to the Department for specific authorizations to perform one of the following operations.

- A. Servicing operations on devices containing radioactive material.
- B. Leak testing of sealed sources except by means of leak test kits.

Each of the above are discussed, in order, in the following:

- A. Servicing Operations. Applicants who want to perform operations on devices involving installation, relocation, maintenance, repair, removal, or disposal, performance of radiation surveys following installation, etc., should provide the following information:
 - 1. The specific device(s) on which the operations are to be performed.
 - 2. A description of each specific operation to be performed.
 - 3. The step-by-step procedures to be followed in performing each operation including a description of the radiation safety which will be followed.
 - 4. The name of each individual who will perform the services.
 - 5. An outline of the training received by each individual who will perform the operation. This training should include instructions in the performance of each specific operation; the step-by-step procedures to be followed; radiation safety and the use of radiation survey instruments, "lock-out" procedures, i.e., procedures for securing the device shutters and/or switches in the closed or shielded position; and, if applicable, personnel monitoring requirements.
 - 6. A description of the qualifications of the individual(s) who provide the training in servicing of devices.
 - 7. If operations are performed which require radiation surveys, (e.g., installations or removals) a description should be provided to show the locations of the radiation measurements and the kinds of records of results to be maintained.

- B. Leak testing of sealed sources. Applicants who want to perform leak tests of sealed sources, i.e., collect the wipe tests and analyze the results, should provide the following information:
1. The name and qualifications of each individual who will perform the leak test.
 2. Procedures and materials to be used in collecting test samples.
 3. The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples.
 4. The instrument calibration procedures, including the name of the manufacturer and model number of each standard source to be used; the nuclide and quantity of radioactive material in each standard source; the step-by-step calibration procedures to be followed; and the name and the experience and training of each individual who will perform the calibrations. In providing information concerning the standard sources used in the calibrations, applicants should provide information concerning the accuracy of each source used. Each source should be, as a minimum, ± 5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Bureau of Standards.
 5. The method, including a sample calculation, used to convert instrument readings to units of activity, e.g., becquerels or microcuries.

APPENDIX B - RADIATION TRAINING GUIDELINES

This appendix describes the information applicants should provide upon application to the Department regarding retraining and refresher training of personnel.

- A. Personnel responsible for radiation safety and who are authorized users of radioactive material should complete the 5-day manufacturer's (e.g. Texas Nuclear or Ohmart) training course.

Retraining should occur at least every seven (7) years. Refresher training should be provided at least annually.

This is the level of training currently required for authorized users, especially if the authorized users would be responsible for the installation or relocation of gauges.

- B. Training is also required for personnel who may work under the supervision of an authorized user (e.g. technicians or operators). Their training should be from two (2) to eight (8) hours long and equivalent to the one-day courses offered by gauge manufacturers.

Retraining should be provided at least annually.

- C. Personnel who may occasionally work in the vicinity of radioactive material such as electricians, mechanics, and other non-radiation workers also need to be trained.

Training for these persons should be from one (1) to four (4) hours long. Topics to be covered include: general radiation safety practices, specific radiation safety procedures to be followed as related to their job function, and emergency procedures.

Training should be provided prior to working in the area of the radioactive material.

- D. All other non-radiation workers and ancillary personnel (management, clerical and janitorial staff) should at least be informed of the existence of radioactive material, the locations of the gauges and who to contact in case of an emergency.

This training should be provided at least annually.